USER MANUAL

1MFA3001 *(Shown)*

FLOWMETER

MODELS:

1MFA, 4MFA, 6MFA and 8MFA Series

8MFA1001 *(Shown)*

SAVE THESE INSTRUCTIONS

Rx ONLY Federal (USA) law restricts this device to sale by or on the order of a physician.

PRECISION MEDICAL®

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RECEIVING / INSPECTION

Remove the Precision Medical, Inc. *Flowmeter* from the packaging and inspect for damage. If there is any damage, DO NOT USE and contact your Provider.

INTENDED USE

The *Flowmeter* is intended for use by physicians, respiratory therapists and other authorized hospital personnel to administer selected doses of medical gases to a patient.

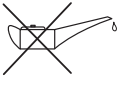
READ ALL INSTRUCTIONS BEFORE USING

This manual instructs a Professional to install and operate the *Flowmeter*. This is provided for your safety and to prevent damage to the *Flowmeter*. If you do not understand this manual, DO NOT USE the *Flowmeter* and contact your Provider.

SAFETY INFORMATION - WARNINGS AND CAUTION

⚠WARNING	Indicates a potentially hazardous situation which, if not avoided, could result in death or serious injury.
⚠CAUTION	Indicates a potentially hazardous situation which, if not avoided, may result in minor or moderate injury.
CAUTION	Used without the safety alert symbol indicates a potentially hazardous situation which, if not avoided, may result in property damage.

Operating Instructions



Symbol for “USE NO OIL”

CE
0473

Symbol indicates the device complies with the requirements of Directive 93/42/EEC concerning medical devices and all applicable International Standards. **(On CE marked Devices ONLY)**

⚠WARNING

- Use Flowmeters only for their “Intended Use” as described in this manual.
- ALWAYS confirm prescribed flow before administering to patient and monitor flow on a frequent basis.
- Flowmeters may contain magnetic, ferrous material that may affect the results of an MRI.

To Reduce the Risk of Fire or Explosion:

- ALWAYS follow ANSI and CGA standards for Medical Gas Products and Flowmeters and Oxygen Handling.
- **DO NOT** use or store oils, greases, organic lubricants or any combustible materials on or near this Flowmeter.
- **DO NOT** use near any type of flame or flammable/explosive substances, vapors or atmosphere.
- **DO NOT** smoke in an area where oxygen is being administered.

⚠CAUTION

- Flowmeters must be operated with the Flow Tube in a vertical, upright position.
- Only personnel instructed and trained in its use should operate this Flowmeter.
- Ensure all connections are tight and leak free.
- Only use oxygen-safe leak detector.
- **DO NOT** autoclave.
- **DO NOT** gas sterilize with EtO (Ethylene Oxide).
- **DO NOT** clean with aromatic hydrocarbons.
- **DO NOT** immerse Flowmeter in any kind of liquid. This will void the warranty.
- The *1MFA3001, 4MFA1001 & 6MFA1001* Flowmeters may have a factory installed restrictor. Prior to use, check Flowmeter labeling for flow restrictions.
- The *1MFA3001, 4MFA1001 & 6MFA1001* Flowmeters contain a glass Flow Tube which is fragile. Special care should be observed to avoid breaking the Flow Tube.

(Continued on Inside)

SPECIFICATIONS

Flow Range	Graduations	Accuracy
0 – 200 cc	20 cc (0-200)	0-100 cc ±10 cc 101-200 cc ±14 cc
0 – 1 l/min	.1 (0-1) l/min	0-1 ±.05 l/min
0 – 3.5 l/min	.125 (0-1) l/min .25 (1-3.5) l/min	0-3.5 ±.15 l/min
0 – 5 l/min	.25 (0-5) l/min	0-5 ±.20 l/min
0 – 6 l/min	.5 (0-6) l/min	0-6 ±.50 l/min
0 – 8 l/min	.5 (0-8) l/min	0-8 ±.25 l/min
0 – 15 l/min	.5 (0-5) l/min 1 (5-15) l/min	0-5 ±.25 l/min 6-15 ±.50 l/min
0 – 26 l/min	1 (2-26) l/min	2-4 ±.50 l/min 5-26 ±10% of reading
0 – 70 l/min	5 (0-70) l/min	0-70 ±10% of reading

Flush Flow is the output of the flowmeter when the flow indicator is beyond the highest calibrated graduation. The Flush Flow range is as indicated on the flowmeter labeling.

Transport / Storage Requirements -40˚F (-40˚C) to 140˚F (60˚C)

The gas and inlet pressures are indicated on the Flow Tube or Flowmeter body.

NOTE: Storage / Transport outside the specified range may cause damage to the flowmeter.

The effect on accuracy of flow due to variations in ambient temperature is standard accuracy +7.3% @ 32°F (0°C) and -3.0% @ 104°F (40°C).

The above Flowmeter models are calibrated at specified inlet pressure, 70°F (21°C), standard atmospheric pressure. International models are calibrated per specifications marked on Flow Tube or Flowmeter body.

Specifications are subject to change without prior notice.

For the most current manual revision
please visit our website: www.precisionmedical.com

Tell us how we are doing!
Visit us at www.precisionmedical.com

OPERATING INSTRUCTIONS

⚠WARNING

Read this User Manual before installing or operating the Flowmeter.

CAUTION

Inspect the Flowmeter for visual damage before use, DO NOT USE if damaged.

NOTE: Precision Medical, Inc. strongly recommends the use of kink proof Cannula.

1. Turn Knob to the “OFF” position.
2. Connect the Flowmeter to the appropriate gas source. The appropriate gas and pressure are specified on the Flow Tube or Flowmeter body.
3. Verify that the Float Ball is at the very bottom of the Flow Tube.

   NOTE: If the Float is not resting at the bottom of the Flow Tube, the product is leaking; consult the “TROUBLESHOOTING” Guide.
4. Adjust Flow:
   To **increase** - Turn Knob **counterclockwise**

   To **decrease** - Turn Knob **clockwise**
5. Set flow by aligning center of Float Ball with indicator lines on the Flow Tube.
6. Adjusting flow beyond the last calibrated indicator line will result in an undetermined flow.
7. To obtain maximum flush flow, turn Knob fully Counterclockwise.

   NOTE: Flush flow is any flow above the last calibrated line on the Flow Tube with an unrestricted flow, as indicated on flowmeter labeling.

CAUTION

- **DO NOT** over tighten Knob when turning off. This will cause damage to the Flowmeter.
- Pressures other than those indicated on the Flow Tube or Flowmeter body may affect the accuracy of the indicated flow.
- Gas Temperatures other than 70° F (21°C) may affect the accuracy of the indicated flow.
- Attaching accessories to the outlet (which may increase resistance to outlet flow) may change indicated flow but will not affect the accuracy of the flow.
- ONLY use appropriate gas specific indexed fittings to connect Flowmeter to gas source. Use Oxygen connections for oxygen Flowmeters; use air connections for air Flowmeters.
- **DO NOT** attempt to repair the *8MFA* Flowmeters. There are no serviceable parts.

CLEANING INSTRUCTIONS

1. Disconnect all connections before cleaning.
2. Clean exterior surfaces of the Flowmeter with a cloth dampened with a mild detergent and water.
3. Wipe dry with a clean cloth.

TROUBLESHOOTING

If the Flowmeter fails to function, consult your Provider or Precision Medical, Inc.

Problem	Probable Cause	Remedy
Will not shut off	• Leak • Defective Valve	• Replace Tetraseal and/or Housing • Replace Body Assembly
Sticking Float Ball	• Debris in Flow Tube	• Clean Flow Tube & Float Ball
Unable to set desired flow	• Blocked Inlet	• Replace Body Assembly
Knob will not turn	• Valve seized	• Replace Body Assembly

8MFA Models DO NOT have serviceable parts.

RETURNS

Returned products require a Returned Goods Authorization (RGA) number. Any product returned to Precision Medical, Inc. must be packaged in a sealed container to prevent damage. Precision Medical, Inc. will not be responsible for goods damaged in transit. Return Policy available on the Internet, www.precisionmedical.com.

REPLACEMENT PARTS *

PART	MODEL #											
	6MFA	4MFA	1MFA									
	1001		3001	3501	4001	1001	8001	5001	1101	1211	2001	9001
Spring	NA		1575	NA								
Washer	NA		1787	NA								
Disc	NA			1009		1114	1009	1114				1009
Housing	1143											
Tetraseal™	1123											
Flow Tube	Kit # 503213	Kit # 503214	Kit # 503215	1012	1152	1010	1021	502459	507573	502117	1011	1031
Float Ball	1576		1005				1029	1005	1154	1154	1005	1029
Body Assembly	1891	1897	502053	505271	504407		504823	504407			504434	504824
Knob	1007										1008	
Holder	506176		NA									

*** 8MFA Models DO NOT have serviceable parts.**
International parts specifications and specific ratings are available upon request.

DECLARATION OF CONFORMITY

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CE 0473

EC REP

REF Flowmeters 1MFA, 4MFA, 6MFA & 8MFA Series

Classification: IIa
Classification criteria: Clause 3.2 Rule 11 of Annex IX of MDD

We hereby declare that an examination of the under mentioned production quality assurance system has been carried out following the requirements of the UK national legislation to which the undersigned is subjected, transposing Annex II, 3 of the Directive 93/42/EEC and Directive 2007/47/EC on medical devices.

We certify that the production quality system conforms to the relevant provisions of the aforementioned legislation, and the result entitles the organization to use the CE 0473 marking on those products listed above.
Applied Standards: *EN 1041, EN 14971, EN ISO 13485, ISO 15001, ISO 15002, ISO 15223-1*

Notified Body: Intertek AMTAC Certification Services Limited CE 0473
Address: Davy Avenue Knowlhill Milton Keynes MK5 8NL, UK
Certification Registration No's: 1126 CE Date of Expiry: 03 August 2017
Devices already manufactured: S/N traceability Device History Records
Validity of DOC: 04 August 2012 to Date of Expiry
Manufacture Representative: Quality Manager
Position: Quality Systems/ISO Representative
Date of Issue: 04 August 2012

LIMITED WARRANTY
AND LIMITATION OF LIABILITY

Precision Medical, Inc. warrants that the Medical Gas Flowmeter (the Product) will be free of defects in workmanship and/or material for the following period:

(a)	Flow Tube and Housing	Lifetime of the product
(b)	Needle Valve	Five (5) years from shipment
(c)	All other parts of the Medical Gas Flowmeter not identified in (a) or (b) above	One (1) year from shipment

Warranty does not cover breakage / abuse.

Should any failure to conform to this warranty appear within the applicable period, Precision Medical, Inc. shall, upon written notification thereof and substantiation that the goods have been stored, installed, maintained and operated in accordance with Precision Medical, Inc.'s instructions and standard industry practice, and that no modifications, substitutions, or alterations have been made to the goods, correct such defect by suitable repair or replacement at its own expense.

ORAL STATEMENTS DO NOT CONSTITUTE WARRANTIES.

The representative of Precision Medical, Inc. or any retailers are not authorized to make oral warranties about the merchandise described in this contract, and any such statements shall not be relied upon and are not part of the contract for sale. Thus, this writing is a final, complete and exclusive statement of the terms of that contract.

THIS WARRANTY IS EXCLUSIVE AND IS IN LIEU OF ANY WARRANTY OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE OR OTHER WARRANTY OF QUALITY, WHETHER EXPRESS OR IMPLIED.

Precision Medical, Inc. shall not under any circumstances be liable for special, incidental or consequential damages including but not limited to lost profits, lost sales, or injury to person or property. Correction of non-conformities as provided above shall constitute fulfillment of all liabilities of Precision Medical, Inc. whether based on contract, negligence, strict tort or otherwise. Precision Medical, Inc. reserves the right to discontinue manufacture of any product or change product materials, designs, or specifications without notice.

Precision Medical, Inc. reserves the right to correct clerical or typographical errors without penalty.

503349 rev5 [t4] 8/14 (?M) Printed in USA